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Published in:
American Heart Journal

Publication date:
2005

Document Version
Publisher's PDF, also known as Version of record

[Link to publication in Tilburg University Research Portal](#)

Citation for published version (APA):
Pedersen, S. S., van Domburg, R. T., Theuns, D. A., Jordaens, L., & Erdman, R. A. M. (2005). Concerns about the Implantable Cardioverter Defibrillator: A determinant of anxiety and depressive symptoms independent of shocks. *American Heart Journal*, 149, 664-669.

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Concerns about the implantable cardioverter defibrillator: A determinant of anxiety and depressive symptoms independent of experienced shocks

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Background Patients with an implantable cardioverter defibrillator (ICD) are at increased risk of anxiety disorders. In turn, anxiety has been identified as a precipitant of ventricular arrhythmias. Anxiety may in part be attributed to concerns about the ICD firing, but the relationship between ICD concerns, psychological morbidity, and shocks has not been systematically investigated. We examined the relative importance of experienced shocks versus subjective concerns about the ICD as determinants of anxiety and depressive symptoms in ICD patients.

Methods Consecutive surviving patients ($n = 182$, response rate = 82%) having had an ICD implanted between October 1998 and January 2003 at the Erasmus Medical Centre Rotterdam were asked to fill in the ICD Patient Concerns Questionnaire and the Hospital Anxiety and Depression Scale. Clinical variables were obtained from the patients' medical records.

Results A total of 55 (30%) patients had received a shock from the ICD. Although patients who had experienced a shock scored higher on ICD concerns, ICD concerns was the only independent determinant of anxiety (odds ratio 6.35, 95% CI 2.84-14.20) and depressive symptoms (odds ratio 2.29, 95% CI 1.06-4.96) adjusting for shocks and all other factors.

Conclusions Patient concerns about the ICD may be an important indicator of psychosocial adjustment. Screening for ICD patient concerns using the ICD Patient Concerns Questionnaire may identify patients at risk for psychological morbidity after ICD implantation. (Am Heart J 2005;149:664-9.)

The implantable cardioverter defibrillator (ICD) was initially developed to prolong survival and prevent sudden cardiac death in patients with ventricular arrhythmias. Indications for ICD therapy have since expanded to include prophylactic treatment,¹ as the MADIT 1 and 2 and the MUSTT demonstrated that prophylactic implantation improves survival in patient subgroups.^{2,3}

Although the medical benefits of the ICD seem unequivocal, ICD implantation may result in adverse psychosocial outcome for particular subgroups of patients as at least 30% manifest clinically significant levels of anxiety and depressive symptoms.^{4,5} Although

this is equivalent to the prevalence in other cardiac populations, some studies have reported higher levels of distress in ICD patients.^{6,7} More importantly, anxiety related to having an ICD may influence the risk of arrhythmic events, as stress and anxiety have been known for some time to be precipitants of arrhythmias.⁸ The association between mood and arrhythmias was also recently demonstrated in 2 preliminary studies that investigated the effects of anxiety and anger as precipitants.^{9,10} Implantable cardioverter defibrillator implantation has also been shown to impact adversely on quality of life (QoL),^{6,11} although a recent review indicates that QoL may improve to preimplant levels at 1-year follow-up.⁵ Consensus as to how long the adjustment period persists may not be achieved until large-scale prospective studies of psychosocial outcome in ICD patients are available.

However, ICD-related fears and concerns, in particular, fears about the ICD firing, are universal and have been identified as a major determinant of psychological distress, impaired QoL, and the extent to which patients experience the ICD implantation as positive.^{5,6,11} The ICD Patient Concerns (ICDC) Questionnaire is a brief and standardized instrument that can be used to assess these concerns and to identify ICD patients at risk for

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Submitted November 10, 2003; accepted June 7, 2004.

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0002-8703/\$ - see front matter

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doi:10.1016/j.ahj.2004.06.031

adverse outcomes in clinical practice.¹² However, the relationship between ICD concerns, actual shocks received, and anxiety and depressive symptoms has not yet been investigated. A relationship between ICD concerns and psychological morbidity would further underscore the pivotal role of patient concerns with reference to ICD-related health complaints and may provide a specific target for intervention.

Therefore, the objectives of the current study were (1) to examine the prevalence of patient concerns about their ICD and (2) to evaluate the relative importance of experienced shocks versus subjective concerns about the ICD as determinants of anxiety and depressive symptoms.

Methods

Patient selection

Patients ($n = 225$) having had an ICD implanted at the Erasmus Medical Centre Rotterdam between October 1998 and January 2003 were asked as part of routine clinical practice to fill in a number of questionnaires to assess their psychological health. Patients were excluded if they were terminally ill ($n = 1$), had brain damage ($n = 1$), were younger than 16 years ($n = 1$), or had too many missing values on questionnaires ($n = 1$). Of the remaining 221 patients, 182 (82% response rate) participated. No statistically significant differences were found between responders and nonresponders on sex and clinical variables ($P > .05$), but nonresponders were younger than responders (52 vs 62 years, $P < .001$). Sociodemographic and clinical characteristics of the patient responders are presented in Table I.

Measures

Variables assessed included sex, age, marital status, education, and working status. Patients were also asked to indicate whether they used psychotropic medication because of stress, anxiety, depressive symptoms, or sleep disturbances. Information on clinical variables (ie, etiology of coronary artery disease, chronic heart failure, antiarrhythmic drug therapy at baseline, time since implantation [in months], number of shocks [appropriate and inappropriate] received since implantation as read from the ICD, in-hospital arrest, and out-of-hospital arrest) was obtained from the patients' medical records.

The ICDC Questionnaire was originally developed in British ICD patients¹² but was translated into Dutch according to standard practice for the purpose of the current study. The original ICDC Questionnaire consists of 20 items that are scored on a 5-point Likert scale from 0 (not at all) to 4 (very much so). The scale yields a score for number of concerns (range 0-20) and a score for severity of concerns (range 0-80). A higher score on both indicates a greater number of concerns and more severe concerns. The scale is divided into 2 subscales, assessing perceived limitations (eg, "Doing activities/hobbies that may cause my ICD to fire") and device-specific concerns (eg, "My ICD firing"). The psychometric properties of the ICDC Questionnaire are good with test-retest reliability (6 weeks) of 0.77 and Cronbach α of .94 for the total questionnaire.¹²

Table I. Sociodemographic and clinical characteristics of the patient responders ($n = 182$)

	n (%)	Mean (SD)	Range
Women	35 (19)		
Age		62 (13)	16-84
Married/partner	144 (79)		
Education			
University or equivalent	8 (4)		
College	56 (31)		
High school/A levels	64 (35)		
Basic education (up to grade 6)	47 (26)		
Not known	7 (4)		
Working	26 (14)		
Using psychotropic medication	47 (26)		
Coronary artery disease etiology	131 (72)		
Chronic heart failure	44 (24)		
Antiarrhythmic drug therapy at baseline	130 (72)		
Time since ICD implantation (m)		55 (35)	8-132
Shocks received since implantation*			
1 Shock	14 (8)		
>1 Shock	41 (23)		
In-hospital arrest	30 (17)		
Out-of-hospital arrest	75 (41)		

*Based on data stored by the ICD.

The Hospital Anxiety and Depression Scale (HADS) was included to assess psychological morbidity and to investigate the discriminant validity of the ICDC Questionnaire.¹³ The HADS assesses anxiety and depressive symptoms by means of 14 items that are answered on a 4-point Likert scale (0-3). The score range for both the anxiety and depressive symptoms subscales is 0 to 21. The HADS has been validated in somatic, psychiatric, and cardiac patients and in the general population and has been shown to be a valid and reliable instrument.¹⁴⁻¹⁷ A cutoff score ≥ 8 for determining caseness on both subscales was used in the current study, as this has been suggested to yield an optimal balance between sensitivity and specificity.¹⁶

Statistical analyses

Principal components analysis (varimax rotation) was used to examine the factor structure of the Dutch version of the ICDC Questionnaire. A scree plot was used as criteria for determining principal components to retain. Factor loadings below 0.45 were suppressed. Cronbach α was calculated to determine the internal consistency of subscales. Pearson correlations were used to examine the discriminant validity of the ICDC Questionnaire against the HADS. Discrete variables were compared with the χ^2 test and are presented as percentages. Continuous variables were compared with the Student t test and are presented as mean values and SD. In the case of multiple comparisons, we used analysis of variance with a post hoc Bonferroni correction. Logistic univariate and multivariate regression analyses were performed to examine determinants of anxiety and depressive symptoms (using a

Table II. Frequency of endorsements, item means (SD), factor loadings, and internal consistency of the ICDC Questionnaire

Items of ICDC Questionnaire	Frequency of endorsement in %*	Mean (SD)	Factor I†	Internal consistency‡
1. My ICD firing	64	1.19 (1.23)	0.63	.72
18. Getting too stressed in case my ICD fires	59	1.31 (1.42)	0.64	.72
13. Symptoms/pain associated with my ICD firing	58	1.27 (1.40)	0.62	.71
12. Having no warning my ICD will fire	51	.96 (1.18)	0.59	.69
8. Time spent thinking about my ICD firing	48	0.82 (1.11)	0.62	.71
15. Not being able to prevent my ICD from firing	46	1.00 (1.34)	0.59	.69
10. Working too hard/overdoing things causing my ICD to fire	43	0.91 (1.27)	0.61	.70
5. Doing activities/hobbies that may cause my ICD to fire	36	0.72 (1.16)	0.55	.66
			eigenvalue I = 4.85	$\alpha = .91$

*Score >0.

†Principal components analysis.

‡Corrected item-total correlations.

cutoff of ≥ 8). In multivariate analyses, we adjusted for sex, age, marital status, time since ICD implantation, shocks, and ICD concerns (with the upper tertile representing high levels of concerns). Odds ratios (OR) with 95% CIs are reported for univariate and multivariate analyses. All statistical tests used were 2-tailed; $P < .05$ was used to indicate statistical significance. All statistical analyses were performed using SPSS 11.5 (SPSS Inc, Chicago, Ill) for Windows.

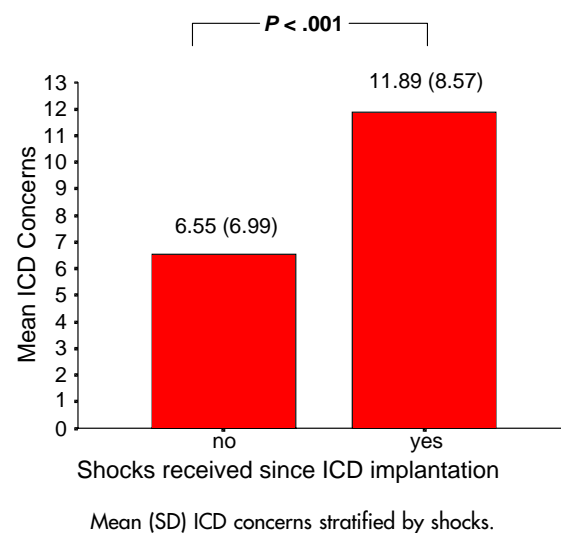
Results

Patient concerns about their implantable cardioverter defibrillator

Because the Dutch version of the ICDC Questionnaire has not previously been used, we first subjected the ICDC Questionnaire to a factor analysis and correlated it with the HADS, a validated measure of anxiety and depressive symptoms.

The Kaiser-Meyer-Olkin measure of sampling adequacy (0.914) and Bartlett test of sphericity (<0.001) indicated that it was appropriate to proceed with factor analysis and that the correlation matrix was suitable for further analysis. The scree plot suggested a 1-factor structure. On the basis of factor loadings, we chose the 10 items that loaded the highest on the unrotated component. These 10 items were subsequently subjected to a reliability analysis, which showed that 2 items did not contribute significantly to the overall variance. Hence, the final Dutch ICDC Questionnaire consisted of 8 items explaining 61% of the variance; all 8 items were related to concerns about the ICD firing (Table II). The internal consistency of the subscale was good with Cronbach $\alpha = .91$ (Table II). Frequency of endorsements (score >0) on the ICDC Questionnaire items ranged from 36% to 64% (Table II). The item with the highest endorsement was "My ICD firing" with 64% of the patients having this concern.

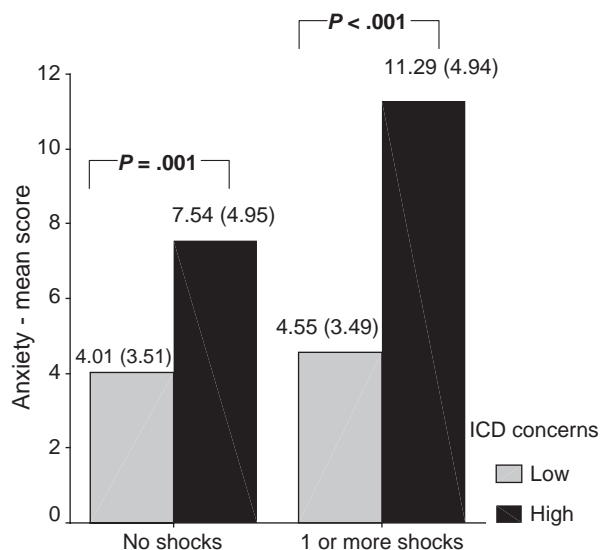
Implantable cardioverter defibrillator concerns as measured by the ICDC Questionnaire correlated

Figure 1

positively with anxiety ($r = 0.61$, $P < .01$) and depressive symptoms ($r = 0.42$, $P < .01$) accounting for 37% and 18% of the variance, respectively. Although there is an overlap between ICD concerns and anxiety and depressive symptoms, the unshared variance of 63% and 82% indicates that the ICDC Questionnaire and the HADS largely measure different constructs.

Because the concerns that patients may have about their ICD may be attributed to the number of shocks they have received, we investigated the relationship between shocks and ICD concerns. Shocks received since implantation were related to ICD concerns; that is, patients who had experienced 1 or more shocks reported significantly more ICD-related concerns com-

Figure 2



Mean (SD) anxiety score stratified by shocks and ICD concerns.

pared with patients who had experienced no shocks (Figure 1).

Shocks versus concerns as determinants of anxiety and depressive symptoms

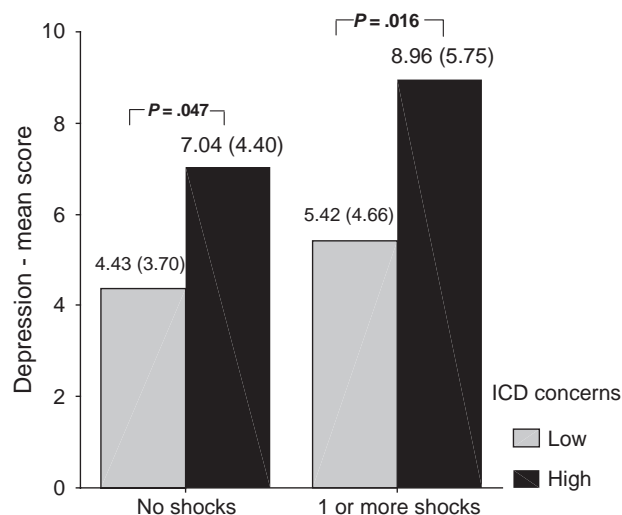
Of the 182 patients, 56 (32%) had anxiety, and 50 (28%) had depressive symptoms.

Patients with more ICD concerns were at higher risk of anxiety (Figure 2) and depressive symptoms (Figure 3) irrespective of whether they had experienced shocks. Anxiety was attenuated in the no-shock/high ICD-concern group compared with the shock/low ICD-concern group ($P = .04$), whereas no statistically significant difference was found between these 2 groups on depressive symptoms.

In univariate analyses, shocks (OR 2.58, 95% CI 1.32-5.03) and ICD concerns (OR 2.18, 95% CI 1.61-2.96) were both associated with increased anxiety. Similarly, ICD concerns were related to increased depressive symptoms (OR 1.41, 95% CI 1.05-1.87). No other variables were associated with anxiety and depressive symptoms in univariate analyses.

In multivariate analyses, high levels of ICD concerns (OR 6.35, 95% CI 2.84-14.20) remained an independent determinant of anxiety adjusting for sex, age, marital status, months since implantation, and shocks. Implantable cardioverter defibrillator concerns were also related to more depressive symptoms (OR 2.29, 95% CI 1.06-4.96) adjusting for all other variables.

Figure 3



Mean (SD) depression score stratified by shocks and ICD concerns.

Discussion

The results of the current study indicate that patient ICD concerns are highly prevalent. Patient concerns about the ICD were a determinant of anxiety and depressive symptoms independent of experienced shocks.

It is noteworthy that regardless of whether patients had received shocks from the ICD, those scoring high on ICD concerns had a higher mean score on both anxiety and depressive symptoms. Implantable cardioverter defibrillator concerns were also associated with a 6-fold increased risk of anxiety and a 2-fold increased risk of depressive symptoms independent of shocks and other factors. These findings suggest that ICD concerns more so than shocks received from the ICD may place patients at risk for psychopathology. Although shocks have previously been shown to increase the risk of psychological distress and adverse QoL,^{11,18,19} the CIDS showed that there may be a dose-response relationship between shocks and distress.¹⁹ In the latter study, only patients who had received ≥ 5 shocks were at risk of adverse outcome. In another recent study of the current patient sample and their partners, we found that the distressed personality—also known as type D personality—was associated with increased anxiety and depressive symptoms in both ICD patients and their partners; this relationship between personality and distress in patients remained despite controlling for shocks.²⁰ Taken together, these findings suggest that we may need to expand our focus beyond looking at shocks as the sole determinant of psychological distress.

Time since ICD implantation could not explain individual differences in anxiety and depressive symptoms. Although others have found that psychological adaptation to the ICD improves over time,²¹ psychopathology in ICD patients has also been found to be unrelated to time since implantation.²² This finding indicates that if concerns are not dealt with early on, they are likely to persist over time. In fact, addressing concerns about the ICD as early as preimplantation may be necessary to reduce psychological morbidity, to enhance QoL, and to reduce the risk of arrhythmic events because emotional states have been shown not only to impact adversely on QoL^{6,11} but also to precipitate arrhythmic events.⁹

We found that ICD concerns can best be measured by an 8-item version of the ICDC Questionnaire because this shortened version accounted for slightly more variance (61% vs 57%) than the original 20-item version.¹² Moreover, the 8-item version was as psychometrically sound as the original 20-item version.¹² This makes it a more optimal instrument to use in clinical practice and in research settings because it poses less of a burden to patients.

The results of the current study should be interpreted with caution, in particular, because of the cross-sectional design of the study. The nature of the design does not allow for the determination of cause and effect and also provides no information about fluctuations over time in concerns and psychological morbidity. We also had no information about previous psychiatric history and the use of psychotropic medication before implantation. Previous psychiatric history is a known predictor of future psychopathology. In addition, we could not make a distinction between appropriate and inappropriate shocks. Inappropriate shocks have been associated with more psychological distress, but this finding was based on only 25 patients, and the determination of appropriateness was based on the patient's subjective interpretation.²³ Although the results are preliminary and should be replicated in prospective studies, in particular, to further disentangle the relationship between anxiety, depressive symptoms, shocks, and ICD concerns, the ICDC Questionnaire seems to be a promising instrument that may be used in clinical practice to identify patients at risk for adverse outcome.

In conclusion, we found that ICD concerns were associated with an increased risk of anxiety and depressive symptoms irrespective of shocks. This finding suggests that we may need to expand our view of indicators of psychosocial adjustment in ICD patients. Large-scale prospective studies that include preimplantation and postimplantation assessments are now warranted to examine the relationship between shocks, concerns, and psychological morbidity. Such studies would shed further light on the role of psychological factors as precipitants of arrhythmias.

The brevity and reliability of the 8-item ICDC Questionnaire make it suitable to use as a research tool and in clinical practice to identify patients at risk who may benefit from psychosocial intervention. Psychosocial interventions targeting the concerns that patients may have about their ICD are also required given our findings that concerns were a determinant of psychological morbidity independent of shocks. The recent preliminary results of a randomized controlled trial of comprehensive cardiac rehabilitation in ICD patients indicate that such a program is safe and leads to an improvement in exercise ability and a reduction in psychological distress.²⁴

We thank Dr Dorothy J. Frizelle and her coauthors for making the ICDC Questionnaire available to us for the purpose of the current study. We are also grateful to the nurses Agnes Muskens-Heemskerk and Esther Zwanenburg-Hogendoorn, the Thoraxcentre, the Erasmus Medical Centre Rotterdam, for their involvement in the project, and Dr Joban Denollet, Department of Psychology and Health, Tilburg University, for his comments on an earlier draft of this paper.

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